



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/802,175

03/17/2004

Theodor Funck

46955.13

3846

23973

7590

04/03/2008

DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER

LIN, JERRY

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

04/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/802,175	Applicant(s) FUNCK, THEODOR	
	Examiner Jerry Lin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments, filed October 3, 2007, have been fully considered and they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

2. Applicants have requested the rejoinder of claims 15-18, in light of the amendments. Applicants state that because the instant claims now require the measurement of at least one macroscopic physical quantity of a sample, the method (group I) cannot be conducted by hand. The Examiner agrees partially. Group I, claims 1-14, may still be practice by another materially different apparatus than the one disclosed in claims 15-18 (group II). While the step of measuring quantitatively one macroscopic physical property requires a device, the steps of correlating, determining or evaluating may be done by hand and do not necessarily require a device for correlating, determining, or evaluating. Thus, the process as claimed can be practiced by another and materially different apparatus or by hand (MPEP § 806.05(e)).

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

Claims 1-14 are under examination.

Claims 15-18 are withdrawn as being drawn to a non-elected invention. The election was made with traverse December 20, 2006.

Inventorship

3. In view of the papers filed October 3, 2007, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding the inventors Inga Zerr, Gisela Feldmann, and Monika Bodemer.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112, 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 3 recites “a relative precision better than 10^{-3} .” However, the instant claim does not include a unit with this numerical value to indicate what this number represents. The Specification on page 4, does include embodiments of what this number may mean, however, these embodiments do not explicitly define the term. Without a unit, it is unclear to what this number is referring.

Response to Arguments

5. Applicants have responded to this rejection by directing the examiner to specification. Applicants state that 10^{-3} means a measurement of the at least one physical with a systemic and statistical error lower than 0.1%. However, as the claims is written, the claim does not indicate that 10^{-3} is to mean statistical error lower than 0.1% and the Examiner cannot import limitations from the claim.

Applicants also state that one of ordinary skill in the art would know what unit is to be assigned depending on the property to be measured. However, the number “ 10^{-3} ” gives no indication that it refers to the statistical error of a property. Thus the instant claims are indefinite.

This rejection is maintained from the previous office action.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding claims 1-13, the instant claims are drawn to a process involving the judicial exception of a computational algorithm. Claims drawn to a judicial exception is non-statutory unless the claims include a practical application of that judicial exception as evidenced by a physical transformation of matter, or if the claimed invention recites a useful, tangible and concrete final result. In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result. See MPEP 2106.

The instant claims do not include a useful, concrete, and tangible result. A useful, concrete, and tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. In the instant case, the claims end with a determining step or an evaluating step. In both instances, the steps indicate that there is an ongoing process. However, this does not necessarily lead to a result. Since there is no final result, the instant claims do not have a useful, concrete, and tangible final result. Examples of amendments to overcome this rejection include amending the claims to identify/recite a concrete result and to recite that the result is outputted to a display or to a user or outputted in a user readable format. However, applicant is reminded that any amendment must be fully supported and enabled by the originally filed disclosure.

Regarding claim 14, the instant claim does contain a physical transformation with is performed before measuring and evaluating. However, the claim is still drawn to a judicial exception as recited in claim 13. Thus, the judicial exception must either result

in a physical transformation or have useful, concrete and tangible result. As explained above the claimed method does not have a useful, concrete and tangible result.

Response to Arguments

8. Applicants have responded to this rejection by stating that measuring the sample is transformative and that a diagnostic characteristic is a useful, concrete, and tangible result. The Examiner disagrees. As written in the claims, the process of measuring sample does not change the sample itself. Whether it requires the action of a person is not the standard for determining a physical transformation. Rather, the action of a person may be seen as a physical step, but it is not a physical transformation.

Secondly, applicants state that a diagnostic characteristic is a useful, concrete and tangible result. However, the instant claims are not limited to useful, concrete and tangible results. Rather, the method may be conducted within a computer and never communicated to the outside world. Thus, there would be no tangible result.

Furthermore, the steps of determining and evaluating indicate a ongoing process that may or may not produce a final result.

This rejection has been modified as necessitated by amendment and newly applied to claims 2, 4, 5, 6, 8, 9, 12, and 14.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1631

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al. (NeuroImage (January 2002) Volume 15, pages 463-473).

The instant claims are drawn to a method of diagnostic investigation including the steps of accommodating a sample in a measuring device, measuring quantitatively for one macroscopic physical property using sound waves, correlating the physical property with reference data that characterizes one condition of the sample, and determining one diagnostic characteristic.

Berg et al. teach a method of measuring quantitatively a macroscopic physical property of a sample using sound waves (pages 467-469) and correlating that physical property with reference data (control group) that characterized one condition of the sample (pages 467-469) and determining one diagnostic characteristic of the sample (pages 467-469) . In addition, the method teaches detecting at least one disease comprising a neurodegenerative disease producing characteristic biomolecules (pages 467-469).

Response to Arguments

11. Applicants have responded to this rejection by amending the claims to include the limitation of accommodating a sample comprising of fluid in measuring device and stating that Berg et al. does not teach this limitation. The Examiner disagrees. The head of a human can be construed as a biological sample that contains fluid.

Furthermore, the instant claims have no recitation that the measurement takes place *in*

vitro or outside a biological organism. This rejection is maintained from the previous office action.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1, 2, 5, 7-9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al. (British Journal of Haematology (1997) Volume 96, pages 168-173) in view of Atkinson et al. (J. Phys. A: Math., Nucl. Gen., (1974) Volume 7, Number 11, pages 1293-1302).

The instant claims are drawn to a method of diagnostic investigation including the steps of accommodating a sample in a measuring device, measuring quantitatively for one macroscopic physical property (such as viscosity) using sound waves, correlating the physical property with reference data that characterizes one condition of the sample, and determining one diagnostic characteristic.

Regarding claims 1 and 2, Lowe et al. teach a method of determining the viscosity of a sample (abstract) and correlating that data with reference data (page 170) to obtain at least one diagnostic characteristic (page 171, left column).

However, Lowe et al. does not teach obtaining this data using sound waves.

Regarding claim 1, Atkinson et al. teaches a method of measuring quantitatively a macroscopic physical property by accommodating a sample in a measuring device (page 1293).

Regarding claims 5 and 7, Lowe et al. teach wherein a difference is determined between a first measure quantity of a sample and the reference measured quantity of a sample (page 170, right column).

Regarding claims 8 and 9, Lowe et al. teach determining the presence of lipids (page 169, left column).

Regarding claim 12, Lowe et al. teach adding an additive (page 169, left column).

All the claimed elements are taught by Atkinson et al. and Lowe et al. One of ordinary skill in the art could have combined the methods with no change in their functions. Each method could be conducted on a sample of blood without impacting the other method. Thus, the method of Lowe et al. and Atkinson et al. could be used in combination to achieve the predictable results of determine the properties of blood.

14. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al. (British Journal of Haematology (1997) Volume 96, pages 168-173) in view of Atkinson et al. (J. Phys. A: Math., Nucl. Gen., (1974) Volume 7, Number 11, pages 1293-1302) as applied to claims 1, 2, 5, 7-9, and 12 above, and further in view of Aarnoudse et al. (Catheterization and Cardiovascular Interventions (2004) Volume 62, pages 56-63).

The instant claims are drawn to a method of diagnostic investigation including the steps of accommodating a sample in a measuring device, measuring quantitatively for one macroscopic physical property (such as viscosity) using sound waves, correlating the physical property with reference data that characterizes one condition of the sample, and determining one diagnostic characteristic. In addition, the instant claims include embodiments where the samples are measured at different temperatures and pressures.

Lowe et al. and Atkinson et al. are applied as above.

However, Lowe et al. and Atkinson et al. do not teach samples are measured at different temperatures and pressures.

Aarnoudse et al. teach measuring at different temperatures and pressures (page 58).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Lowe et al. and Atkinson et al. with Aarnoudse et al.'s device to gain the benefit of experimenting with blood under conditions that resemble an *in vivo* situation. Aarnoudse et al. teach that their model mimics the heart and blood flow (page 57). Using this device would aid one of ordinary skill in the art to study blood and how properties of blood are effect *in vivo* conditions. Thus to measure physical properties of blood in an experiment, one of ordinary skill in the art would have been motivated to combine Aarnoudse et al.'s *in vitro* model with the method of Lowe et al. and Atkinson et al.

Withdrawn Rejections

14. Applicant's arguments and amendments, filed October 13, 2007, with respect to the rejection of claim 13 under 35 U.S.C §112 2nd Paragraph and the rejection of claims 1, 2, 4-9 and 12 as being unpatentable over Lowe et al., Cohen-Bacrie, and Miwa have been fully considered and are persuasive. The rejection of claim 13 under 35 U.S.C §112 2nd Paragraph has been overcome by amendment and the rejection is withdrawn. The rejection of claims 1, 2, 4-9 and 12 as being unpatentable over Lowe et al., Cohen-Bacrie, and Miwa has been withdrawn because Cohen-Bacrie's method does require a flow rate, which Lowe et al. cannot have since their sample is *in vitro*.

Contact Information

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571)272-2561.

The examiner can normally be reached on 7:30-4:00pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L./

Examiner, Art Unit 1631

/John S. Brusca/

Primary Examiner, Art Unit 1631